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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/065,929	12/02/2002	John J. Heine	1372.66.PRC	6456
21901	7590	- 09/13/2006	EXAMINER	
SMITH HOPEN, PA 180 PINE AVENUE NORTH OLDSMAR, FL 34677			LIN, JERRY	
			ART UNIT	PAPER NUMBER
			1631	
DATE MAILED: 09/13/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/065,929

Applicant(s)

HEINE ET AL.

Examiner

Jerry Lin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 27, 2006 has been entered.

Status of the Claims

Claims 1-13 are under examination.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-5, 9, 10, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giger et al. (US 5,133,020) in view of Huo et al. (US 6,282,305).

The instant claims are drawn to a method of determining breast cancer risk by establishing the risk probability value associated with a patient, applying a computer algorithm to find abnormalities, determining a threshold for identifying false positives, and adjusting the threshold in response to the risk probability value.

Regarding claims 1 and 13, Giger et al. teach identifying a standard threshold of the computer algorithm for identifying false positive abnormalities (column 6, lines 33-column 9, line 10); and adjusting the threshold for identifying false positives based on the risk associated with a patient (column 12, line 58-column 13, line 7).

However, Giger et al. does not specifically teach calculating breast cancer risk.

Regarding claim 1 and claim 12, Huo et al. disclose a method which includes establishing a risk probability with a patient with factors such as age wherein the risk probability is between 0 and 1 (column 5, lines 55-63; column 6, line 25-40); applying a computer algorithm to find abnormalities in a patient's mammogram (column 9, lines 30-48).

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the references of Huo et al. with Giger et al. to gain the

Art Unit: 1631

benefit of using known risk analysis methods to improve the prognosis or diagnosis of breast cancer based on mammograms. Giger et al. indicates that the threshold may be adjusted for the risk assessment of a patient for better evaluation of a mammogram (column 12, line 58-column 13, line 7). Based on their recommendation, one of ordinary skill in the art would be motivated to search for a method of calculating breast cancer risk. Huo et al. provides methods of calculating breast cancer risk. One of ordinary skill in the art would be motivated to combine the references of Giger et al. and Huo et al. in order to carry out Giger et al.'s method as he indicates.

Regarding claims 2 - 4, Huo et al. also discuss relative risk and absolute risk (column 3, lines 25-40) as well as include specific odds ratios in regard to breast cancer (column 3, line 66 - column 4, line 5).

Regarding claim 5, Huo et al. disclose determining parenchymal patterns (breast tissue density) (column 8, line 61-column 9, line 7; column 7, lines 18-37); integrating breast tissue density in the risk probability value (column 8, line 61-column 9, line 7; Figure 10).

Regarding claim 9, Huo et al. also disclose a data entry interface (Figure 13; column 29, lines 10-61); digitally acquiring the patient's mammogram (column 37, claim 45; column 29, lines 10-61); applying the algorithm to the mammogram (column 37, claim 45; column 29, lines 10-61).

Regarding claim 10, Huo et al. disclose storing risk factors on electronic storage medium with digitally acquire mammogram (column 37, claim 45 – column 38, claim 48; column 29, lines 10-61).

Response to Arguments

5. The Applicants have responded to this rejection by distinguishing the threshold values used in Giger et al. and the claimed invention. The Applicants state that the claimed invention uses adjusts the threshold for determining if a mammogram contains abnormalities. In contrast, the Applicants argue, Giger et al. identify abnormalities first and then adjust the threshold to determine if that abnormality is benign or malignant.

However, the Examiner disagrees with the Applicant with their characterization of the claims. As the method is claimed, a risk probability value is determined, the computer algorithm then finds the abnormalities, and then a threshold is applied. Although the Applicants are stating that the claimed invention performs the method steps in a different order, the written claims recite something to the contrary. The limitations argued by the applicants are not found in the instant claims, and the Examiner cannot import limitations from the specification into the claims. With Examiner's interpretation of the claims, Giger et al. does anticipate the claims as recited.

This rejection is maintained from the previous Office Action.

6. Claims 6 -8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giger et al. (US 5,133,020) in view of Huo et al. (US 6,282,305) in view of Wang (US 6,266,435).

The instant claims are drawn to a method of determining breast cancer risk by establishing the risk probability value associated with a patient, applying a computer algorithm to find abnormalities, determining a threshold for identifying false positives, and adjusting the threshold in response to the risk probability value. The algorithm also includes flagging mammograms or recommending a course of action.

Giger et al. and Huo et al. is applied as above.

Neither Giger et al. or Huo et al. teaches flagging mammograms or recommending a course of action.

Regarding claims 6 and 7, Wang discloses flagging (marking or annotating) positive or negative results of mammograms (column 8, lines 47-65).

Regarding claim 8, based on the results of the method, the physician recommends a course of action, which would include more invasive procedures for high probability of breast cancer or less invasive procedures for low probability of breast cancer (column 2, lines 51-55).

Regarding claim 11, Wang discloses presenting the results with computer aided enhancement (column 7, lines 37-56).

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the references of Huo et al. and Giger et al. with Wang to gain the benefit of electronically annotating the mammogram images. Wang discloses that his method offers to advantage of offering a physician or technician additional information to aid in the interpretation of the mammogram image as well as to aid in determining the best course of action for a patient (Wang, column 4, lines 1-16).

Art Unit: 1631

Huo et al. and Giger et al. both disclose methods of interpreting digital mammogram images to aid physicians. Thus, one of ordinary skill in the art would be motivated to combine the methods of Huo et al., Giger et al., and Wang to provide a complete set of tools to aid a physician in interpreting mammograms.

Response to Arguments

7. The Applicants have responded to this rejection by stating that Giger et al. does not teach the threshold as claimed in the invention. Please see above for the Examiner's response.

This rejection is maintained from the previous Office Action.

Conclusion

This is a Request for Continued Examination of applicant's earlier Application No. 10/065929. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

Art Unit: 1631

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00am-6:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Representatives are available to answer your questions daily from 6 am to midnight (EST). When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center at (800) 786-9199.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

JL

